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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/101,413	08/07/98	STAUSS	H	RPMS102

HM22/1011

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EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	14

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/101,413	Stauss, H.
Examiner	**Group Art Unit**
Gerald Ewoldt	1644

☒ Responsive to communication(s) filed on *Jul 24, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-18, 20-43, and 45-49* is/are pending in the application.

Of the above, claim(s) *10-13, 20-43, and 45-49* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9 and 14-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3 and 4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment, filed 7/24/2000, is acknowledged.

2. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald R. Ewoldt, Group Art Unit 1644.

3. Claims 1-9 and 14-18 are pending and being acted upon.

4. Applicant again argues that the finding of lack of unity of invention is improper. The argument has been fully considered but has not been found convincing for the reasons of record set forth in Paper No 10.

5. Applicant argues that the declaration as filed is proper. While a new declaration is not required for the purpose of properly claiming benefit of foreign priority, a new declaration is required to meet the requirements of 37 CFR 1.63(c).

6. In view of Applicant's amendment and response, filed 7/24/00, the rejection of Claim 1 under the second paragraph of 35 U.S.C. 112 for the recitation of "HLA Class I or equivalent", has been withdrawn. Only the following rejections remain.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-9 and 14-18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claim 1 it is unclear what the term "diseased cells which cells contain or are <u>associated with</u> an abnormal molecule or abnormally elevated amount of a molecule" means. It is unclear what the term "cells are <u>associated with</u> means".

Applicant's arguments have been fully considered but have not been found convincing. Applicant argues that the phrase would be clear to one skilled in the art. However, Applicant has provided no additional evidence to support said argument, or clarification as to just exactly what cells might be "associated with" an abnormal molecule. Thus, the claim remains indefinite.

B) It is unclear what the term "abnormal molecule" means.

Applicant's arguments have been fully considered but have not been found convincing. Applicant argues that the term includes mutant molecules, transformed molecules, abnormally glycosylated molecules, and virus infected molecules. However, Applicant has still failed to define the metes and bounds of the term. Defining some of the terms included in the definition provides no insight into what terms are actually excluded from the definition, i.e., the metes and bounds of the definition.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-9, 14, 16, and 18 stand rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 5,928,639 (Slavin et al.) as evidenced by Wu et al. (*J. Biol. Chem.*, 1995).

Applicant's arguments, filed 7/24/00, have been fully considered but have not been found convincing, for the reasons set forth previously in Paper No. 10. Applicant argues that the '639 patent (Slavin et al.) does not teach a method using CTL that recognize a particular molecule and that the method is not peptide specific. However, it is a fundamental concept of immunology that CTL recognition is peptide specific and that CTL do recognize particular molecules. Thus the properties exploited in the instant application are inherent to the CTL of the reference teaching.

Applicant further argues that the '639 patent does not each the specific tumor associated antigens recited in the claims and that the reference actually teaches a more preferred method of tumor therapy. The purpose of the Wu et al. reference was to demonstrate that leukemic cells express the elected species, GATA1 and WT1. Thus, the properties claimed and exploited in the instant application are inherent to leukemic cells and therefore not patentably distinct. Further, while the reference may teach a preferred method, it additionally teaches the method of the instant claims.

Applicant further argues that the while the '639 patent does teach a graft versus leukemia effect, it does not measure graft versus host disease. However, Applicant argues limitations not found in the claims.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-9 and 14-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kohler et al. (*Cancer Immunol. Immunother.*, 1988) or U.S. Patent No. 5,994,523 (Kawakami et al.), in view of Yin et al. (*Eur. J. Immunol.*, 1994) or Huang et al. (*Cancer Immunol. Immunother.*, 1994), U.S. Patent No. 5,928,639 (Slavin et al.) or Wu et al. (*J. Biol. Chem.*, 1995).

Applicant's arguments, filed 7/24/00, have been fully considered but have not been found convincing, for the reasons set forth previously in Paper No. 10. Applicant again argues that the methods taught by the '639 patent, as well as by Kohler et al. are not antigen- specific. As discussed supra, it is a fundamental concept of immunology that CTL recognition is antigen-specific.

Applicant argues that the Kawakami et al. reference teaches only a self-HLA restricted response. However, the reference was used in the rejection to teach the use of CTL against abnormal molecules, not to teach an alloresponse.

Applicant argues that the response of the Yin et al. reference is "promiscuous". While the response may appear "promiscuous" from the macroscopic view, absent evidence to the contrary, and in view of the fundamental one receptor-one epitope concept of immunology, each CTL is believed to bind a single antigen; thus the response is actually antigen-specific.

Applicant argues that the Huang et al. reference does not provide "any clue" as to how to induce a peptide-specific T cell response. Said clue, however is not required because peptide-specificity is inherent to a T cell response.

Applicant concludes by arguing that the references do not teach how to make a specific response and that the rejection is based on impermissible hindsight. As previously discussed, all CTL responses are antigen-specific, the instant application offers only further characterization of a known method. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. So long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

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Technology Center 1600
October 10, 2000

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